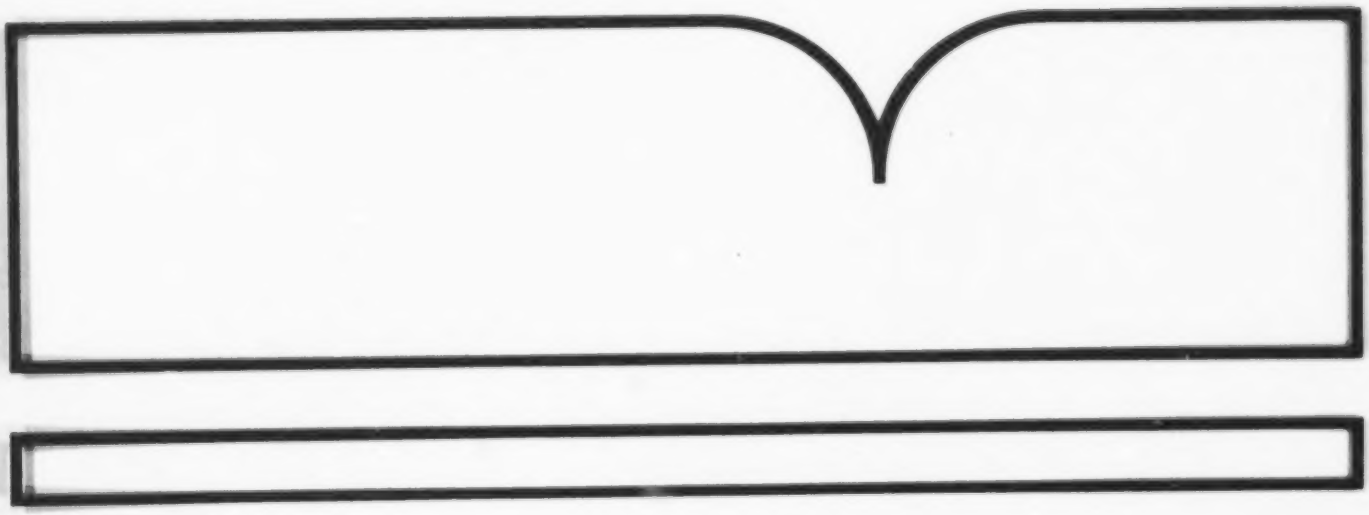
PB87-110276

Guidance for the Reregistration of Pesticide Products Containing Bromacil as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

30 Sep 82



U.S. Department of Commerce
National Technical Information Service

540/RS-86-165

PB87-110276

GUIDANCE PACKAGE FOR

REREGISTRATION OF PESTICIDE PRODUCTS

IN COMPLIANCE WITH

Bromacil and its lithium salt

REGISTRATION STANDARD

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

REGISTRATION DIVISION

WASHINGTON, D.C.

September 30, 1982

REPRODUCED BY
U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL
INFORMATION SERVICE
SPRINGFIELD, VA. 22161

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. Recipient's Accession No.
4. Title and Subtitle: Guidance for the Reregistration of Pesticide Products Containing BROMACIL as the Active Ingredient.			5. Report Date: Issued Sept. 30, 1982
			6.
7. Author(s): EPA, Office of Pesticide Programs, Registration Division			8. Performing Organization Rept. No.: 540/RS-86- 165
9. Performing Organization Name and Address: US Environmental Protection Agency, Office of Pesticide Programs, Registration Division TS-767C, 401 M Street, SW, Washington, D. C. 20460			10. Project/Task/Work Unit No.
			11. Contract(C) or Grant(G) No. (C) (G)
12. Sponsoring Organization Name and Address: Same as #9			13. Type of Report & Period Covered
			14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manufacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement	19. Security Class (This Report)	21. No. of Pages
Publicly Available	Unclassified	47
	20. Security Class (This Page) Unclassified	22. Price

(See ANSI-Z39.18) See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

Table of Contents

Page

Section

I. Introduction 1
II. Data Compensation 1
III. Submission of Generic Data under FIFRA 3
IV. Requirement for Submission of Product-Specific Data Under FIFRA § (3)(c)(2)(B) 27
V. Submission of Revised Labeling, Classification, and Packaging Information 27

A. Label Contents 28
1. Product Name 28
2. Company Name and Address 28
3. Net Contents 28
4. EPA Registration Number 28
5. EPA Establishment Number 28
6. Ingredient Statement 28
6A Pounds per Gallon Statement 28
7. Front Panel Precautionary Statements 29
7A Child Hazard Warning Statements 29
7B Signal Word 29
7C Skull and Crossbones and Word Poison 29
7D Statement of Practical Treatment 29
7E Referral Statement 29
8. Side/Back Panel Precautionary Labeling 29
8A Hazard to Humans and Domestic Animals 30
8B Environmental Hazard 30
8C Physical or Chemical Hazard. 30
9. Product Classification 31
9B Omitted . . . . . .
9C Misuse Statement 34
10A Re-entry Statement 34
10C Storage and Disposal Block 34
10D Directions for Use 34
B. Collateral Information 35
C. Special (Child-Resistant) Labeling Requirements 35

VI. Instructions for Submission 35

VII. Statement on Agency Position Regarding Court Suits Involving FIFRA § (3)(c)(1)(D) 37

APPENDICES

II-1	Data Compensation Statement: Reregistration
II-2	Product-Specific Data Report
III-1	Generic Data Exemption Report
III-2	FIFRA § 3(c)(2)(B) Summary Sheet
III-3	Statement of Willingness to Enter Into an Agreement With Other Registrants For Development of Data
V-1	40 CFR § 162.10 Labeling Requirements
V-2	Table of Labeling Requirements
V-3	Physical-Chemical Hazards Labeling Statement
V-4	40 CFR § 162.11 Use Classification
V-5	Storage and Disposal Statements
V-6	40 CFR § 162.16 Special Packing Requirements

I. INTRODUCTION

This guidance package has been prepared to provide you, the registrant, with specific information with which you may maintain in effect your current registration(s) that is subject to this Registration Standard. (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirement in this standard, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this package, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following package within the timeframes outlined.

II. Data Compensation

As part of your application for reregistration, you must comply with the data requirements of FIFRA Section 3(c)(1)(D) by including with your application a completed Data Compensation Statement (Appendix II-1). That form includes:

A. A statement that you offer to pay compensation to other persons with regard to the application to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D).

B. A statement acknowledging that, if EPA approves your application for reregistration, the approval will be based on EPA's consideration of the following:

1. All the existing "generic" data* which, according to the table, "Generic Data Requirements for Manufacturing-Use and End-Use Products" (Table A at the end of Section III), are relevant to EPA's evaluation of the registrability of your product (taking into account your product's composition and formulation category, and the uses of your product which its label will permit).

2. The "product-specific" data* which you have listed on the form entitled "Product-Specific Data Report" (Appendix II-2).

C. A statement that you have furnished an offer to pay compensation to the person(s) listed below in the manner specified:

1. Persons to whom offers must be made: An offer must be furnished to each person who, according to the Standard, was the original submitter of any of the generic or product-specific data upon which approval of your application will be based, except that:

a. You need not furnish an offer with respect to data that were originally submitted prior to January 1, 1970.

---

* For an explanation of the terms "generic" data and "product-specific" data, see pp. 3-4 of the Registration Standard.

b. FIFRA Section 3(c)(2)(D) provides that you need not furnish an offer with respect to any "generic" data, if your product is an end-use product and if its active ingredient will be present in your product solely because of the incorporation into your product of another registered manufacturing-use product which contains that active ingredient and which you purchase from another producer. Note: This exemption does not cover "product-specific" data.

c. Many data submitters have informed EPA that they do not wish to receive offers under FIFRA Section 3(c)(1)(D). The various persons who submitted data listed in the Standard's bibliography who have not waived their rights to receive offers will be listed in Tables A, B, or C. You will be required to write those companies if the data in those tables are required to support your formulations and uses.

Companies that may need to receive offers
to pay for 3(c)(1)(D)

A) E.I. du Pont de Nemours and Company
Legal Department
Wilmington, DE 19898

B) NALCO Chemical Company
2901 Butterfield Road
Oak Brook, IL 60521

C) Platt Chemical Company
150 South Main
Fremont, NE 68025

d. You need not furnish an offer to any person with whom you have already agreed in writing concerning the amount (if any) and terms of compensation payable under FIFRA Section 3(c)(1)(D) in connection with the reregistration of your product.

e. You need not furnish an offer with respect to any data unless the data were submitted to EPA (or its predecessor agencies) to support an application for registration, amended registration, or reregistration; to support or maintain in effect an existing registration; to support an application for an experimental use permit; or to support a petition for a tolerance, food additive regulation, or other clearance under the Federal Food, Drug and Cosmetic Act which was a prerequisite to a FIFRA registration action.

2. Form of the offer: You must furnish each person who is entitled to receive an offer the following information, in writing:

   a. A notification of your intent to apply for reregistration under the Standard, and the name, active ingredient, and intended uses of your product.

   b. An offer to pay the person compensation, with respect to approval of your application, to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D), and an offer to begin negotiations to set the amount and terms of compensation.

   c. Your name, mailing address, and telephone number.

III. REQUIREMENT FOR SUBMISSION OF GENERIC DATA UNDER FIFRA SECTION 3(c)(2)(B)

A. This portion of the Guidance Package is a Notice issued under the authority of FIFRA Section 3(c)(2)(B). EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified in an attachment to the cover letter accompanying this Guidance Package. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

   EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. Entitlement of Certain End-Use Registrants to An Exemption.

   Under the circumstances described in this section III(B), EPA will refrain from suspending the registration of an end-use product even if its registrant does not submit data in response to this Notice. EPA's position is based on the intent of Congress as set forth in FIRRA Section 3(c)(2)(D). Under that section, if generic data on an active ingredient had already been submitted to EPA, an applicant for registration of an end-use product would be excused from the normal Section 3(c)(1)(D) requirement of submitting or citing, and offering to pay compensation for, those data as a condition of obtaining registration. To qualify for that exemption, the active ingredient must be present in the product solely as a result of the incorporation into the product (during formulation or packaging) of a manufacturing-use product containing that active ingredient registered under FIFRA and purchased from another producer. The object of this provision is to simplify data compensation by

making compensation for the generic data on the active ingredient an element of the market cost of registered manufacturing-use products, so that formulators or other registrants who purchase such products need not separately offer to pay for data on the active ingredient.

EPA has concuded that these principles should also apply in the closely analogous situation presented by this Section 3(c)(2)(B) requirement. However, principles of fairness to those who incur expenses of data generation and submission make it necessary to ensure that a registrant be exempted from this data submission requirement only if the active ingredient in the registrant's product is being purchased from a firm which is required to submit (or to offer to share in the cost of obtaining) the generic data required by this Notice.

If a registrant who is subject to this Section 3(c)(2)(B) Notice fails to comply with the data submission requirement, the Administrator may suspend its registration. However, this authority is discretionary, and the Administrator will not exercise it to suspend a registration if:

1. the registration is for an end-use product, as opposed to a manufacturing-use product; and

2. the active ingredient in the end-use product is present solely as the result of the incorporation into that product (during formulation or packaging) of a manufacturing-use product which contains that active ingredient, is registered under FIFRA, and is purchased by the registrant; and

3. the registrant completes and executes a "Generic Data Exemption Statement" (Appendix III-1) for the end-use products, and submits it to EPA within 90 days of receipt of this Notice; and

4. one or more registrants actually do undertake to submit, and do submit, all the data required by this Notice.

C. What Generic Data Must be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products to which the Standard applies, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA approved protocols, the Pesticide Registration Guidelines* or data collected under the approved

* The Pesticide Registration Guidelines were proposed in two separate publications. On July 1, 1978, EPA issued proposed guidelines for product chemistry, environmental chemistry, and fish and wildlife hazard testing, 43 FR 29696. The Agency published proposed human hazard guidelines on August 22, 1978, 43 FR 37336.

protocols of the Organization for Economic Cooperation Development (OECD) which are yet to be published. If you wish not to develop data which are necessary to support the continued registration of certain uses appearing in your current labeling, you may delete those uses at the time you submit your revised labeling for registration.

Also, for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.). These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data, which are required on each formulation regardless of type of formulation. Product-specific data are further explained under Section IV of this document and are specified in Tables B and C at the end of this Section.

D. Options Available For Complying with Requirements to Submit Data. You must submit to EPA within 90 days of your receipt of this Notice a completed copy of the form entitled "FIFRA § 3(c)(2)(B) Summary sheet" (Appendix III-2) for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice.

1. Attach a completed "Generic Data Exemption Statement" (Appendix III-1).

2. Notify EPA that you will submit the data, and either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

3. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option you must at the same time notify EPA which registrant(s) are parties to the agreement. At least one of the parties to the agreement must respond to this Notice in the manner specified by paragraph III(D)(1) above.

4. File with EPA a completed "Statement of Willingness to Enter Into An Agreement With Other Registrants for Development of Data" (Appendix III-3)*.

5. Request that EPA amend your registration by deleting the uses for which the data are needed.

6. Request voluntary cancellation of the registration(s) of your product(s) for which the data are needed.

E. Procedures for Requesting Changes In Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted.

If the test procedures you plan to use deviate from (or are not specified in) registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

---

* FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data, or a cost-sharing agreement between all such registrants, is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if: (1) a registrant has informed the Agency of its intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

If you want, or think that you will need, more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. You must strive to meet the deadline for submitting the required data while EPA considers your request.

TABLE A

Generic Data Requirements for Bromacil: Product Chemistry

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.61-3	Product Identity Disclosure of Ingredients	Yes	95% Technical Grade Bromacil	Partially[1]/	00013313[A]/	Yes (6 months)*
163.61-4	Description of Manufacturing Process	Yes	95% Technical Grade Bromacil	Yes	05014430	No
163.61-5	Discussion of Formation of Unintentional Ingredients	Yes	95% Technical Grade Bromacil	No	--	Yes (6 months)*
163.61-6	Declaration and Certification of Ingredient Limits	Yes	95% Technical Grade Bromacil	Partially[2]/	00013313[A]/	Yes (6 months)*
163.61-7	Product Analytical Methods and Data	Yes	95% Technical Grade Bromacil	Yes	05016141 05002583 00013324 00013372[B]/ GS0040001	No

1) Information must be submitted on identity and quantity of impurities and inerts on each registered product.

2) A certification of ingredient limits must be applied on each registered product.

* March 1983.

A/ du Pont Company

B/ NALCO Chemical Company

TABLE A

Generic Data Requirements for Bromacil: Product Chemistry

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.61-8	Physical/Chemical Properties					
163.61-8(c)(1)	Color	Yes	95% Technical Grade Bromacil	No	--	Yes (6 months)*
163.61-8(c)(2)	Odor	Yes	95% Technical Grade Bromacil	No	--	Yes (6 months)*
163.61-8(c)(3)	Melting Point	Yes	95% Technical Grade Bromacil	No	--	Yes (6 months)*
163.61-8(c)(4)	Solubility	Yes	95% Technical Grade Bromacil	No	--	Yes (6 months)*
163.61-8(c)(5)	Stability	Yes	95% Technical Grade Bromacil	No	--	Yes (6 months)*
163.61-8(c)(6)	Octanol/Water Partition Coefficient	Yes	95% Technical Grade Bromacil	No	--	Yes (6 months)*
163.61-8(c)(7)	Physical State	Yes	95% Technical Grade Bromacil	Yes	00013313[A]/	No
163.61-8(c)(8)	Density or Specific Gravity	Yes	95% Technical Grade Bromacil	No	--	Yes (6 months)*
163.61-8(c)(10)	Vapor Pressure	Yes	95% Technical Grade Bromacil	No	--	Yes (6 months)*

TABLE A

Generic Data Requirements for Bromacil and Lithium Salt of Bromacil: Toxicology

Guidelines Citation	Name of Test	Are Data Required?	Composition[1]/	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
TOXICOLOGY						
163.81-1	Acute Oral Toxicity	Yes	80% Wettable Powder Bromacil	Yes	000022077C/ GS00400003	No
163.81-2	Acute Dermal Toxicity	Yes	80% (same)	Yes	00022078C/ 00013243	No
163.81-3	Acute Inhalation Toxicity	Yes	80% (same)	Yes	00022080C/ 00013243	No
163.81-4	Primary Eye Irritation	Yes	80% (same)	Yes	00013243	No
163.81-5	Primary Dermal Irritation	Yes	80% (same)	Yes	00022081C/	No
163.81-6	Dermal Sensitization	Yes	80% (same)	Yes	00013243C/	No
163.82-1	Subchronic Oral	Yes	80% (same)	Yes[2]/	00013243 GS0040011	No
163.82-2	Subchronic Dermal Toxicity	Yes	80% (same)	No[3]/		No
163.82-2	Subchronic Inhalation	Yes	80% (same)	Yes[4]/		No

1/ Testing on the 80% bromacil wettable powder satisfies the toxicology data requirements for the lithium salt.
2/ A 90-day feeding study is sufficient to satisfy this requirement.
3/ Acute dermal toxicity study available. The product is not intended for purposeful application to skin.
4/ Acute inhalation study available.
C/ Platt Chemical Company

TABLE A

Generic Data Requirements for Bromacil and Lithium Salt of Bromacil: Toxicology

Guidelines Citation	Name of Test	Are Data Required?	Composition[1]/	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
TOXICOLOGY						
163.83-1	Chronic Feeding	Yes	80% W.P. Bromacil	Partially[5]/	GS0040008 GS0040003	Yes (3 yrs)*
163.83-2	Oncogencity	Yes	80% (same)	Partially[6]/	GS0040011	Yes (3 yrs)*
163.83-3	Teratogenicity	Yes	80% (same)	Partially[7]/	GS0040008	Yes (3 yrs)*
163.83-4	Reproduction	Yes	80% (same)	Yes	GS0040008	No
163.84-2 through -4	Mutagenicity	Yes	80% (same)	Yes	05013518 05013519 00013309 05016657 05014905 GS0040007	
163.85-1	Metabolism (Identification of Metabolites)	Yes	80% (same)	Yes	05002771 00013298 00013273	

5/ Additional dog feeding study using technical grade of bromacil required.

6/ Additional mouse study begun in 1979.

7/ Additional study in a second species is required using technical grade of bromacil.

* September 1985.

TABLE A

Generic Data Requirements for Bromacil: Residue Chemistry

Guidelines Citation	Name of Test	Are These Data Required by the Guidelines?	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
--	Uptake, distribution and metabolism in plants	Yes	Yes	00013202 05002415 05014750	No
--	Metabolism in food-producing animals	Yes	Yes	05002192	No
--	Analytical methods	Yes	Yes	05013999 05014217 05019944	No
--	Residue data: raw agricultural commodities	Yes	Yes	00013205 00013293[A]/ 00013321 GS0040011	No
--	Residue data: processed foods	Yes	Yes	GS0040003	No
--	Residue data: meat, milk, poultry and eggs	N/A	No	--	No*
--	Storage stability data for residues	N/A	No	--	No*

*Samples show no residues at limit of detection.

TABLE A

Generic Data Requirements for Bromacil and its Lithium Salt: Ecological Effects

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.71-1	Avian Single-Dose Oral LD_{50}	Yes	Technical	No		Yes (6 months) 1/*
163.71-2	Avian Dietary LD_{50} Manufacturing Process	Yes	Technical	Yes	00013295	No
163.72-1	Fish Acute LC_{50}	Yes	Technical	No		Yes (6 months) 2/*
163.72-2	Acute Toxicity to Aquatic Inverte-brates	Yes	Technical	No		Yes (6 months) 2/*

1/ Data on technical bromacil will also satisfy the requirement for a study on the lithium salt.

2/ Data on the lithium salt product will also have to be provided.

* March 1983.

TABLE A

Generic Data Requirements for Bromacil and its Lithium Salt: Ecological Effects

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.72-3	Acute Toxicity to Estuarine & Marine Organisms	Yes	Technical	No		Yes[1]/ (1 yr)*
163.72-4	Fish, Early Life-Stage, Aquatic Invertebrate Life Cycle.	Yes	Technical	Yes		Reserved[2]/

1/ Bromacil use patterns on citrus and pineapple require estuarine studies. Studies would include acute shrimp, and oyster embryo larva or shell deposition, and an estuarine fish such as spot. Separate study not required on the lithium salt.

2/ Data from EFB will determine the need for a daphnia life cycle and partial chronic brook trout and mysid shrimp life cycle studies due to use in citrus, pineapple, and drainage ditches.

* September 1983.

TABLE A

Generic Data Requirements for Bromacil: Environmental Fate

Guidelines Citation	Name of Test	Data Required[1]/	Composition	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.161-1	Hydrolysis	A, B, C, D	Radiolabeled Analytical Grade or Technical Grade of Active Ingredient (RLAG/TGAI)	No	-	Yes/36 months)*
163.161-2	Photodegradation in Water	A, B, C, D	RLAG/TGAI	Partially[2]/	05013650	Yes/36 months*
163.161-3	Photodegradation on Soil	B, C,	RLAG/TGAI	No	-	Yes/36 months*
163.161-4	Photodegradation in Air	B, C,	RFP*	No	-	No [2A]/
163.162-1	Aerobic Soil Metabolism	A, B, C	RLAG/TGAI	Partially[3]/	00013299 05013204 05016176	Yes/36 months*
163.162-2	Anaerobic Soil Metabolism	C	RLAG/TGAI	Partially[4]/	05013204 05016176	Yes/36 months*
163.162-4	Aerobic Aquatic Metabolism	D	RLAG/TGAI	No	-	Yes/36 months*
163.162-3	Anaerobic Aquatic Metabolism	D	RLAG/TGAI	No		Yes/36 months*

Footnotes: See Page 19

TABLE A

Generic Data Requirements for Bromacil: Environmental Fate

Guidelines Citation	Name of Test	Data Required[1]/	Composition	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitt Under FIFRA 3(c)(2)(B)? If so, due when?
Reserved	Effects of Microbes on Pesticides	A, B, C, D				Reserved[5]/
163.161-1	Leaching	A, B, C, D	RLAG/TGAI	Partially[6]/	05012167 05017170 GS0040005 00020782	Yes/36 months)*
163.164-1	Field Dissipation Terrestrial	A, B, C	Representative Formulated Product (RFP)	No[7]/	See footnote[7]/	Yes/36 months
163.164-2	Field Dissipation Aquatic and Aquatic Impact	D	RFP	No	00024374[8]/ 05020742	Yes/36 months*
163.164-5	Dissipation Long-Term Studies	C	RFP	No	-	Yes/36 months*
163.165-3	Accumulation Irrigated Crops	D	RFP	No	-	Yes/36 months*
163.165-4	Laboratory Studies - Fish[9]/	A, B, C, D	RLAG/TGAI	No	-	Yes/36 months*
163.165-4	Field Accumulation Aquatic[10]/	D	RFP	No	-	Yes/36 months*

Footnotes: See Page 19

TABLE A
Generic Data Requirements for the Lithium Salt of Bromacil: Environmental Fate

Guidelines Citation	Name of Test	Data Required[1]/	Composition	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)?
163.161-1	Hydrolysis	A, D	Radiolabeled Analytical Grade or Technical Grade of Active Ingredient (RLAG/TGAI)	No	-	Yes/36 months**
163.161-2	Photodegradation in Water	A, D	RLAG/TGAI	Partially	05013650	Reserved
163.162-1	Aerobic Soil Metabolism	A	RLAG/TGAI	Partially	00013299 05013204 05016176	Reserved
Reserved	Effects of Microbes on Pesticides	A, D				Reserved
Reserved	Effects of Microbes on Pesticides	A, D				Reserved

Footnotes: See Page 19

TABLE A
Generic Data Requirements for the Lithium Salt of Bromacil: Environmental Fate

Guidelines Citation	Name of Test	Data Required[1]/	Composition	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)? If so, due when?
163.163-1	Leaching	A	RLAG/TGAI	Partially	05012167 05017170 GS0040005 00020782	Reserved
163.164-1	Field Dissipation Terrestrial	A	Representative Formulated Product (RFP)	No	-	Reserved
163.164-2	Field Dissipation Aquatic and Aquatic Impact	D	RFP	No	00024374 05020742	Reserved
163.165-3	Accumulation Irrigated Crops	D	RFP	No	-	Reserved
163.165-4	Laboratory Studies-Fish	A, D	RLAG/TGAI	No	-	Reserved
163.165-4	Field Accumulation Aquatic	D	RFP	No	-	Reserved
163.162-4	Aerobic Aquatic	D	RLAG/TGAI	No	-	Reserved
163.162-3	Anaerobic Aquatic Metabolism	D	RLAG/TGAI	No	-	Reserved

Footnotes: See Page 19

TABLE A

Generic Data Requirements for the Lithium Salt of Bromacil: Environmental Fate (continued)

Footnotes:

1/ This column specifies the following use patterns for which the data are required: A = Noncrop; B = Tree Fruit and Nut Crop; C = Field and Vegetable Crop; D = Aquatic Noncrop.

2/ The portion of the photodegradation in water study that is concerned with the irradiation of bromacil in a photoreactor for 6 days can be used to support the identification of the photoproducts part of the data requirement. It cannot be used to support the rate of photolysis of bromacil in the water part of the data requirement because the study was not conducted for long enough. Additionally, that portion of the study concerning the irradiation of 5-bromo-6-methyluracil and 5-bromo-1,3,6-trimethyluracil, probable photodegradation products of bromacil, can also be used in support of the identification of the photoproducts part of the photodegradation in water data requirement.

2A/ Required by the Agency on a case-by-case basis depending upon data derived from laboratory volatility tests; see Section 163.163-2(b)(2) of Guidelines. However, this data requirement is waived due to the non-volatile nature of bromacil.

3/ These studies partially satisfy the data requirements for aerobic soil metabolism by providing data on the rate of degradation of bromacil in silt loam and sandy loam soils. They do not satisfy the data requirement for the formulation and decline of degradation products or the identification of degradation products other than $^{14}CO_2$.

4/ These studies partially satisfy the data requirements for anaerobic soil metabolism by providing data on the rate of degradation of bromacil in a sandy loam soil. They do not satisfy the data requirements for the formation and decline of degradation products or the identification of degradation products other than $^{14}CO_2$.

5/ The requirement for these data are being reserved pending the development and modification of test protocols.

6/ These studies fulfill the rapid leaching part of the mobility data requirement by providing leaching information on bromacil in silty clay loam, loamy sand and loam soils. To totally fulfill the mobility data requirement, the following studies are required: (1) A mobility study to assess the leaching potential of bromacil and its degradates after the pesticide has been aged in a sandy soil or a soil representative of the use area. This will satisfy the data requirements for A (Noncrop) and B (Tree Fruit and Nut Crop) use patterns. (2) A batch equilibrium (adsorption/desorption) study on one aquatic sediment obtained from, or representative of, the use area. This will satisfy the data requirements for D (Aquatic noncrop) use pattern. (3) A "rapid" and aged leaching study using the soil typical of pineapple growing areas (in Hawaii only). This will satisfy the C (Field and Vegetable Crop) use pattern data requirements.

TABLE A

Generic Data Requirements for the Lithium Salt of Bromacil: Environmental Fate (continued)

Footnotes:

7/ Although 11 field dissipation studies were evaluated to be valid, none of the studies can be used to partially or totally satisfy the field dissipation data requirement:

a. Studies with MRID 00013252, 00013299 and Gardiner et al., 1969, J. Agr. Food Chem. 17 (5):980-986, combined into one study, cannot be used to partially or totally satisfy field dissipation (mobility) data requirement because ^{14}C-bromacil was used. The test substance required to be used is a typical end-use product.

b. The study with the MRID 05016506 cannot be used to partially or totally satisfy field dissipation data requirement because the soil sampling procedure was inappropriate to determine the pattern of decline of bromacil (Hyvar X) or pattern of formation and decline of degradation products for each single or multiple application.

c. Studies with MRID 05017207 and 05017104, combined into one study, for the reasons given cannot be used to partially or totally satisfy field dissipation data requirement as in "b" above.

d. Study with MRID 05013837 cannot be used to partially or totally satisfy field dissipation data requirement because of the objective of the study: To evaluate the probable magnitude of the problem of leaching of pesticides into ground water under extreme conditions: a sandy soil low in organic matter, a persistent and mobile herbicide applied at a high rate, plentiful rainfall and a water table within 6 meters (a worst-case evaluation study).

e. Studies with MRID 05014211, 05021869, 05015334, 05014972, 05017359, 05015975 and 05015217 cannot be used to partial or totally satisfy field dissipation data requirement because bioassay methods were used. Bioassay methods are non-specific, consequently they are only able to detect phytotoxic residues and are not able to accurately determine levels of either parent compound or its residues.

8/ Two field dissipation aquatic studies were evaluated and found to be valid; however, neither study can be used to partially or totally fulfill the data requirement because the identity of the test substance is unknown. In addition, soil samples were not taken immediately after application, consequently the extent of degradation cannot be determined. Degradation products were neither determined nor identified.

9/ Field accumulation studies in aquatic non-target organisms are required to support the registration of each end-use product:

- o That is intended for forestry use, aquatic non-crop use, or aquatic impact use that results in direct discharges.
- o For which data from a laboratory fish accumulation study are required by Section 163.165-4.
- o For which no tolerance or action level for fish has been grated.

10/ Data requirements for these studies may or may not be required based on the outcome of a hydrolysis study.

* September 1985
** March 1983

TABLE B

Product-Specific Toxicology Data Requirements for Manufacturing Use Products of Bromacil and the Lithium Salt of Bromacil

Guidelines Citation	Name of Test	Are These Data Required by the Guidelines?	Test Substance	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)?
163.81-1	Acute Oral	Yes	80% WP Bromacil	Yes	000022077C/ GS0040003	No
163.81-2	Acute Dermal Toxicity	Yes	80%	Yes	00022078C/ GS0040003	No
163.81-3	Acute Inhalation Toxicity	Yes	80%	Yes	00022080C/ GS0040003	No
163.81-4	Primary Eye Irritation	Yes	80%	Yes	GS0040003	No
163.81-5	Primary Dermal Irritation	Yes	80%	Yes	00022081C/ GS0040003	No
163.81-6	Dermal Sensitization	Yes	80%	Yes	GS0040003	No

1/ Data from bromacil would satisfy requirements for the lithium salt of bromacil.

TABLE B

Product-Specific Manufacturing Use Products Data Requirements for Bromacil and the Lithium Salt of Bromacil: Product Chemistry

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)?
163.61-3	Product Identity Disclosure of Ingredients	Yes	Each Formulation	Partially[1]/	000013313[A]/	Yes/6 months*
163.61-4	Description of Manufacturing Process	Yes	Each Formulation	No	--	Yes/6 months*
163.61-5	Discussion of Formation of Unintentional Ingredients	Yes	Each Formulation	No	--	Yes/6 months*
163.61-6	Declaration and Certification of Ingredient Limits	Yes	Each Formulation	Partially[2]/	000013313[A]/	Yes/6 months*
163.61-7	Product Analytical Methods and Data	Yes	Each Formulation	Yes	05016141 05002583 00013324 00013372[B]/ GS0040001	No

1) Updated information must be supplied on identity and quantity of impurities and inerts.

2) A certification of ingredient limits must be supplied.

* Table B, Product Chemistry, data due March 1983.

TABLE B

Product-Specific Manufacturing Use Products Data Requirements for Bromacil and the Lithium Salt of Bromacil: Product Chemistry

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)?
163.61-8	Physical/Chemical Properties					
163.61-8(c)(7)	Physical State	Yes	Each Formulation	No		Yes/6 months*
163.61-8(c)(8)	Density or Specific Gravity	Yes	Each Formulation	No		Yes/6 months*
163.61-8(c)(12)	Storage Stability	Yes	Each Formulation	No		Yes/6 months*
163.61-8(c)(13)	Flammability	Yes	Each Formulation	No		Yes/6 months*
163.61-8(c)(14)	Oxidizing/Reducing Action	Yes	Each Formulation	No		Yes/6 months*
163.61-8(c)(15)	Explosiveness	Yes	Each Formulation	No		Yes/6 months*
163.61-8(c)(16)	Miscibility	Yes	Each Formulation	Yes		Yes/6 months*
163.61-8(c)(18)	Corrosion Characteristics	Yes	Each Formulation	No		Yes/6 months*

TABLE C

Product-Specific End-Use Products Data Requirements for Bromacil and the Lithium Salt of Bromacil: Product Chemistry

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)?
163.61-3	Product Identity Disclosure of Ingredients	Yes	Each Product	Partially[1]/	000013313[A]/	Yes/6 months*
163.61-4	Description of Manufacturing Process	Yes	Each Product	No	--	Yes/6 months*
163.61-5	Discussion of Formation of Unintentional Ingredients	Yes	Each Product	No	--	Yes/6 months*
163.61-6	Declaration and Certification of Ingredient Limits	Yes	Each Product	Partially[2]/	000013313[A]/	Yes/6 months*
163.61-7	Product Analytical Methods and Data	Yes	Each Product	Yes	05016141 05002583 00013324 00013372[B]/ GS0040001	No

1) Formula information on identity and quantity of impurities and inerts must be updated.

2) Ingredient limits - maximum and minimum - must be certified.

* Table B, Product Chemistry, data due March 1983.

TABLE C

Product-Specific End-Use Product Data Requirements for Bromacil and Lithium Salt of Bromacil: Product Chemistry

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)?
163.61-8	Physical/Chemical Properties					
163.61-8(c)(1)	Color	Yes	Each Product	No		Yes/6 months*
163.61-8(c)(2)	Odor	Yes	Each Product	No		Yes/6 months*
163.61-8(c)(7)	Physical State	Yes	Each Product	Yes	00013313^/	No
163.61-8(c)(8)	Density or Specific Gravity	Yes	Each Product	No		Yes/6 months*
163.61-8(c)(11)	pH	Yes	Each Product	No		Yes/6 months*
163.61-8(c)(12)	Storage Stability	Yes3/	Each Product	No		Yes/6 months*
163.61-8(c)(13)	Flammability	Yes	Each Product	No		
163.61-8(c)(14)	Oxidizing/Reducing Action	Yes	Each Product	No		Yes/6 months*
163.61-8(c)(15)	Explosiveness	Yes	Each Product	No		Yes/6 months*
163.61-8(c)(16)	Miscibility	Yes	Each Product	No		Yes/6 months*
163.61-8(c)(17)	Vircosity Coefficient	Yes (if liquid)	Each Product	No		Yes/6 months*

3/ Required for combustible liquids only.

* Table C, Product Chemistry, data due March 1983

TABLE C

Product-Specific Toxicology Data Requirements for End-Use Products of Bromacil and the Lithium Salt of Bromacil

Guidelines Citation	Name of Test	Are These Data Required by the Guidelines?	Test Substance	Does EPA Have Data To Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)(2)(B)?
163.61-8(c)(18)	Corrosiveness Action	Yes	Each Product	No		Yes/6 months*
163.61-8(c)(19)	Dielectric breakdown voltage	Yes	Each Product	No		Yes/6 months*
163.81-1	Acute Oral	Yes	Each Product	Yes	000022077C/ GS0040003	No
163.81-2	Acute Dermal Toxicity	Yes	Each Product	Yes	00022078C/ GS0040003	No
163.81-3	Acute Inhalation Toxicity	Yes	Each Product	Yes	00022080C/ GS0040003	No
163.81-4	Primary Eye Irritation	Yes	Each Product	Yes	GS0040003	No
163.81-5	Primary Dermal Irritation	Yes	Each Product	Yes	00022081C/ GS0040003	No
163.81-6	Dermal Sensitization	Yes	Each Product	Yes	GS0040003	No

IV. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA UNDER FIFRA § 3(c)(2)(B)

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA section 3(c)(2)(B) EPA has determined that you must submit these data to EPA in order to maintain the registration of your product(s). All these data must be submitted not later than 6 months after you receive this Guidance Package.

The tables entitled "Product-Specific Data Requirements for Manufacturing-Use Products" and "Product-Specific Data Requirements for End-Use Products," which appear as Tables B and C of this Guidance Package, permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under § 3(c)(2)(B)."

In some cases the Tables may note that EPA already possesses some or all of the product-specific data needed to evaluate your product; if that is the case, we encourage you to elect to cite that data in lieu of generating and submitting new data. (You must comply with FIFRA Section 3(c)(1)(D) if you elect to cite existing data; see Section II of this Guidance Package.)

The Tables also indicate that in some cases, a product-specific data requirement for a group of similar products can be satsified by a single test.

Your application for registration must include a completed copy of the form entitled "Product-Specific Data report" (Appendix II-2), stating the methods you are using to comply with the product-specific data requirements.

V. LABELING, CLASSIFICATION AND PACKAGING INFORMATION

The Agency has determined to require applicants for registration to amend their product's labeling to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standarized to avoid user confusion.

As part of your application for reregistration, you must submit draft labeling revised to be consistent with: your product-secific data; the precautionary statements and use directions, and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10], as indicated by the following paragraphs of this section of the Guidance Package. The labeling must be submitted within 6 months of your receipt of this Guidance Package.

If you fail to submit revised labeling and packaging information complying with this section, EPA will issue a notice of intent to cancel your registration under FIFRA §6(b)(1).

A. Label Contents

40 CFR Section 162.10 (Appendix V-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix V-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix V-1 [40 CFR §162.10(b)].

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix V-1 [40 CFR §162.10(c)].

Item 3. NET CONTENTS - A net contents statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix V-1 [40 CFR §162.10(d)].

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No." or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix V-1 [40 CFR §162.10(e)].

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix V-1 [40 CFR §162.10(g)].

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various sized labels, as set forth in the Regulations. It should be noted that labeling requlations now being drafted require a minimum 8 point (3mm) type size for all print on a label. When the guidelines are finalized, the below list may be modified accordingly.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	8 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	10 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix V-1 [40 CFR §162.10(h)(1)(ii)].

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix V-1 [40 CFR §162.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned toxicity category I on the basis of oral, inhalation or dermal toxicity the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix V-1 [40 CFR §162.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity categories I, II, and III. See Appendix V-1 [40 CFR §162.10(h)(1)(iii)].

Item 7E. REFERRAL STATEMENT - The statement "See Side (or back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix V-1 [40 CFR §162.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and

that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix V-1 [40 CFR §162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix V-1 [40 CFR §162.10(h)(2)(i)].

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazards and the appropriate precautions to avoid potential accident, injury or damage. See Appendix V-1 [40 CFR § 162.10(h)(2)(ii)].

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are rquired to appear on the label if it meets the criteria in Appendix V-3. The requirement is based on the results of the flash point determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mxture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flash point greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches, using the methd specified in 40 CFR §163.61-8(c)(13)(ii);

ii. There is no flash back; and

iii. The flash point of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the item "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) that may detract from the precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazard of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. PRODUCT CLASSIFICATION: CLASSIFICATION LABELING REQUIREMENTS AND COMPLIANCE SCHEDULE - Section 3(d) of FIFRA requires that all pesticide formulations/uses be classified for either general or restricted use, and that those uses classified as restricted be limited to use by certified applicators or persons under their direct supervision (or subject to such other restrictions as may be imposed by regulation).

In Chapter 2 of the registration standard, the Agency has: (1) indicated certain formulations/uses to be restricted based either on a previous classification determination made through the optional procedures of 40 CFR §162.30 or based on data already available to the Agency, or (2) indicated certain formulations/uses to be unrestricted based on data already available to the Agency, or (3) reserved any classification decision until appropriate short-term data are submitted. Uses have not been classified for general use at this time because such a decision requires an evaluation of chronic data most of which have yet to be generated.

The product-specific data required by the Standard should be used by each registrant to make a classification determination following the criteria of 40 CFR §162.11(c) (Appendix V-4). The draft label(s) submitted to the Agency as part of your application should reflect this determination and must be consistent with the terms of 40 CFR §162.10 and this guidance package with respect to label language and format for restricted use products. (No label changes with respect to classification are required for products with unrestricted uses.) The rationale supporting a classification proposal by the registrant that differs from a classification determination found in the Standard should be submitted with your application.

During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 162.11(c). You will be notified of the Agency's classification evaluation.

A. Classification Labeling Requirements

1. Unrestricted Uses - No label changes with respect to a classification statement are necessary for those formulations/uses that are unrestricted.

2. Restricted Uses - Pesticide products bearing directions for use for formulations/uses classified restricted shall bear statements of restricted use classification on the front panel as described below:

   a. Front panel statement of restricted use classification.

      i. At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in 40 CFR §162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement, "Restricted Use Pesticide" shall appear.

      ii. Directly below this statement on the front panel, a summary statement of the terms of restrictions shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

3. Some But Not All Uses Restricted - If you determine that some uses should be classified RESTRICTED and some uses should be unrestricted, several courses of action detailed below are available:

   i. You may delete all RESTRICTED uses and submit a draft label of the registration of your product to reflect only those uses that are unrestricted.

   ii. Unrestricted uses may appear on a RESTRICTED label, but not vice versa. Therefore, you have the option of using a RESTRICTED USE label bearing all of your directions for use. If you choose this option, you may <u>not</u> distinguish those uses that are not unrestricted from those that are RESTRICTED.

   iii. You may register two separate products with identical formulations, one containing only unrestricted uses and

the other RESTRICTED uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the product names will be assigned separate registration numbers.

iii. You may register two separate products with identical formulations, one containing only unrestricted uses and the other RESTRICTED uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the product names will be assigned separate registration numbers.

B. Compliance Schedules

1. Unclassified uses - None.

2. Restricted uses - The compliance schedule for restricted use products begins only after the approved label is returned to you as follows:

a. No product with a use classified for restricted use under this first phase of reregistration may be released for shipment by the registrant or producer after the 120th day after the date of acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label or has supplemental labeling affixed or is accompanied by supplemental labeling. For the purposes of the first phase of reregistration, supplemental labeling means:

i. an adhesive sticker containing the restricted use statement specified in 40 CFR 162.10(j)92) and also found in this section;

ii. a separate form containing the product name as it appears on the restricted use statement specified in 40 CFR § 162.10(j)(2) and also found in this section, and

iii. the approved new label.

b. No product with a use classified for restricted use under this first phase of reregistration may be distributed or sold by retailers or other persons after the 270th day after the acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label or has supplemental labeling affixed or is accompanied by supplemental labeling.

c. No product with a use classified for restricted use under this first phase of reregistration may be released for shipment by the registrant or producer after the 270th day after the acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label.

d. In cases where a registrant chooses to delete product uses classified as restricted under the first phase of reregistration, no such product may be released for shipment by the registrant or producer after the 180th day after acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label.

e. No product with a use classified as restricted under this first phase of reregistration may be advertised without including the restricted use classification after the 120th day after the acceptance of the label submitted in conjunction with your application.

Brochures, technical pamphlets and similar material which are in final printed form on the data of acceptance of the new label may be distributed only for 270 days from the date of acceptance.

Item 9C. MISUSE STATEMENT - The following statement is required on your label: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Appendix V-1 [40 CFR §162.10 (1)(2)(ii)].

Item 10A. RE-ENTRY STATEMENT - If there is a reentry statement for your product, that statement will be set forth in the second chapter of the standard.

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically on your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix V-5 of the latest specific storage and disposal product labels.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix V-5 [40 CFR §162.10].

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers and other graphic printed matter which are referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. They should be made part of the response to this notice and submitted for review.

C. Special (Child-Resistant) Labeling Requirements

As required in 40 CFR 162.16 (Appendix V-6), any pesticide that is released for shipment by the registrant after March 9, 1981, must be in special packaging if:

(1) its labeling permits residential use;

(2) it has not been classified for restricted use; and

(3) it meets the toxicity criteria of 40 CFR 162.16(c)(2).

Additional information on child-resistant packaging is being developed and will be mailed to you shortly.

VI. Instruction for Submission

All applications prepared in response to this Notice should be addressed as follows:

Robert J. Taylor PM-25
Phone No. (703) 557-1800
Registration Division
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

For each affected product for which continued registration is desired, you must:

A. Within 90 days from receipt of this package, submit the "FIFRA" Section 3(c)(2)(B) Summary Sheet (Appendix III-2) with appropriate attachments.

B. Within 6 months from receipt of this package you must submit:

1. "Application for Amended Pesticide Registration" (EPA Form 8570-11).

2. "Confidential Statement of Formula" (EPA Form 8570-4).

3. "Data Compensation Statement: Reregistration" (Appendix II-1).

4. Product Speific Data Report (Appendix II-2).

5. Two copies of any required product-specific data.

6. Two copies of draft labeling, including the label and associated brochures. If the current accepted labeling conforms to the requirements of the guidance package and the results of the short term data, the registrant can submit such labeling. Otherwise, the labeling should be in draft form. The draft labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mock-up of the labeling suitable for storage in 8 1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front and side panels, and the intended type sizes of the text.

7. A progress report on the development of generic mid-term and long-term data.

C. Within 24 months from the receipt of this package you must submit:

1. All required generic mid-term data (Table A).

2. A progress report on the development of generic long-term data (Table A).

D. Within 42 months from the receipt of this package you must submit the generic long-term data as committed (Table A).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

VIII. STATEMENT of AGENCY POSITION REGARDING COURT SUITS INVOLVING FIFRA SECTION 3(c)(1)(D)

Several companies have used EPA in an attempt to block implementation of FIFRA Section 3(c)(1)(D), which allows EPA to consider one firm's data in support of reregistration of another firm's product. EPA considers all available generic data in preparing a registration standard. If the companies are successful in the litigation, they could then use the reregistration process as a means of forcing competitors off the market. EPA does not intend to allow the reregistration requirement to be distored in this fashion. If your application for reregistration would be affected by this litigation, you will receive further information from EPA before the time your application must be submitted to EPA.

Appendix II-1

DATA COMPENSATION STATEMENT: REREGISTRATION

EPA Reg. No.:_____

Product Name:_____

Applicant's Name & Address:_____

_____

_____

Date of application for reregistration:_____

Registration Standard for products containing:_____

Date Reregistration Standard Issued:_____

Date Reregistration Guidance Package Issued:_____

In connection with applicant's application for reregistration under the Registration Standard and Guidance Package identified above:

(A) Applicant offers to pay compensation to other persons to the extent required by sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

(B) Applicant understands and acknowledges that if EPA approves the application, the approval, will be based solely on EPA's consideration of:

(1) All the generic data which, according to the Registration Standard and Guidance Package identified above, were found relevant to EPA's evaluation of the registrability of applicant's product (taking into account the product's composition and formulation category, and the uses its label will permit); and

(2) The product-specific data listed on the form entitled "Product-Specific Data Report" which is part of this application.

(3) Applicant states that offers to pay compensation have been furnished to the persons and in the form specified by the Guidance Package identified above.

Dated: _____

Name of registrant's
authorized representative: _____
(signature)

_____
(typed)

PRODUCT-SPECIFIC DATA REPORT APPENDIX II-2

EPA Registration No. _____

Reg. Std for _____
Date Reg. Std. Issued: _____
Guidance Package Date: _____

Registration Guideline No.	Name of Test	Test not required for my Product Listed Above (check below)	I am complying with Data Requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MR ID #	Submitting Data (attached) (check below)	
163.61-3	Product Identitity and disclosures ingredients				
-4	Description of manufacturing process				
-5	Discussion on formation of unintentional ingredient				
-6	Declaration and certification of ingredient limits				
7	Product analytical methods and data				
163.61-8(1)	Color				
-8(2)	Odor				
-8(3)	Melting Point				
-8(4)	Solubility				
-8(5)	Stability				
-8(6)	Octanol/water partition coefficient				
-8(7)	Physical State				
-8(8)	Density or specific gravity				
-8(9)	Boiling Point				
-8(10)	Vapor Pressure				
-8(11)	pH				

Registration Guideline No.	Name of Test	Test not required for my Product Listed Above (check below)	I am complying with Data Requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MR ID #	Submitting Data (attached) (check below)	
-8(12)	Storage Stability				
-8(13)	Flammability				
-8(14)	Oxidizing or reducing action				
-8(15)	Explosiveness				
-8(16)	Miscibility				
-8(17)	Viscosity				
-8(18)	Corrosion characteristics				
-8(19)	Dielectric breakdown voltage				
163.71-5(1)	Cage or pen field test				
-5(2)	Full-scale field test				
163.71-1	Fish acute LC_{50}--rainbow trout and bluegill				
-2	Acute toxicity to aquatic invertebrates				
-3	Acute toxicity to estuarine and marine organisms				
-6(a)(1)	Short term simulated field test				
-6(a)(2)	Long term simulated field test				
163.81-1	Acute oral toxicity				
-2	Acute dermal toxicity				
-3	Acute inhalation toxicity				
-4	Primary eye irritation				
-5	Primary dermal irritation				
-6	Dermal sensitization				

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Bromacil Standard

00013202 Gardiner, J.A.; Barrier, G.E. (1964?) Uptake and Metabolism of 2-14C-Labeled Bromacil by Young Orange Trees. (Unpublished study received Mar 10, 1966 under 6F0499; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:090394-N)

00013205 E.I. du Pont de Nemours and Company (1966) Results of Tests on the Amount of Residue in Crops Grown on Treated Soil: Bromacil. Summary of studies 090253-G through 090253-I. (Unpublished study received Nov 15, 1966 under 6F0499; CDL:090253-F)

00013243 Zapp, J.A., Jr. (1965) Toxicological Information: Bromacil: 5-Bromo-3:-sec:-butyl-6-methyluracil. (Unpublished study received Aug 24, 1965 under 352-287; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:002903-L)

00013273 E.I. du Pont de Nemours and Company (1966) Analysis of Urine from Bromacil Production Workers. (Unpublished study received Nov 22, 1966 under 352-87; CDL:002921-D)

00013293 E.I. du Pont de Nemours & Company (1972) Data Supporting Use of Hyvar X Bromacil Weed killer in Pineapple in Hawaii. (Unpublished study received Apr 24, 1974 under 352-287; CDL:023287-A)

00013295 Dieterich, W.H. (1965) Acute Oral Toxicity--Mallard Ducks, Bobwhite Quail: Project No. 201-154. (Unpublished study received Nov 22, 1965 under 352-287; prepared by Hazleton Laboratories, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:100405-A)

00013298 Gardiner, J.A. (19??) Metabolites of Bromacil in Rat Urine. (Unpublished study received Feb 28, 1966 under 352-287; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL: 107599-C)

00013299 Gardiner, J.A. (19??) Laboratory Exposure of 2-14C-Labeled Bromacil to Moisture, Light, and Nonsterile Soil. (Unpublished study received Feb 28, 1966 under 352-287; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:107599-D)

00013309 McGahen, J.W.; Hoffmann, C.E. (1965) Absence of Mutagenic Effects of 3- and 6-Alkyl-5-bromourocil Herbicides on a Bacteriophage. (Unpublished study received Nov 1, 1965 under unknown admin. no.; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:107587-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Bromacil Standard

00013313 E.I. du Pont de Nemours & Company (1977) Bromacil Technical. (Unpublished study received Nov 5, 1976 under 352-325; CDL: 226812-A)

00013321 E.I. du Pont de Nemours & Company (1963) Residue Data Uracil Herbicides--Citrus Fruits. (Unpublished study received Feb 25, 1964 under 352-EX-67; CDL:123347-E)

00013324 Roberts Consolidated Industries, Incorporated (1972) Method of Analysis for Bromacil: Bromacil (5-Bromo-3:-sec:-butyl-6-methyl-uracil) in Formulated Materials. Method dated Mar 27, 1972. (Unpublished study received Dec 2, 1976 under 1203-55; CDL:227290-A)

00013372 Nalco Chemical Company (19??) Bromacil and Pentachlorophenol in Herbicide Formulations. (Unpublished study received Nov 9, 1977 under 1706-104; CDL:232180-A)

00020782 Day, E.W. (1976) Laboratory Soil Leaching Studies with Tebuthiuron. (Unpublished study received Feb 18, 1977 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:095854-I)

00022077 Raltech Scientific Services, Incorporated (1979) Oral Defined LD50. (Unpublished study received Oct 25, 1979 under 34704-52; submitted by Platte Chemical Co., Fremont, Nebr.; CDL:241218-A)

00022078 Raltech Scientific Services, Incorporated (1979) Defined Dermal LD50. (Unpublished study received Oct 25, 1979 under 34704-52; submitted by Platte Chemical Co., Fremont, Nebr.; CDL:241218-B)

00022080 Biesemeier, J.A.; Argevine, D.M. (1979) Inhalation--EPA. (Unpublished study received Oct 25, 1979 under 34704-52; prepared by Raltech Scientific Services, Inc., submitted by Platte Chemical Co., Fremont, Nebr.; CDL:241218-D)

00022081 Raltech Scientific Services, Incorporated (1979) Prim. Skin Irritation. (Unpublished study received Oct 25, 1979 under 34704-52; submitted by Platte Chemical Co., Fremont, Nebr.; CDL:241218-E)

00024374 Smith, A.E.; Grover, R.; Emmond, G.S.; et al. (1975) Persistence and movement of Atrazine, Bromacil, Monuron, and Simazine in intermittently-filled irrigation ditches. Canadian Journal of Plant Science 55(?/Jul):809-816. (Also in unpublished submission received Jul 19, 1978 under 201-403; submitted by Shell Chemical Co., Washington, D.C.; CDL:234470-U)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Bromacil Standard

05002192 Gutenmann, W.H.; Lisk, D.J. (1970) Metabolism and excretion of bromacil in milk of dairy cows. Journal of Agricultural and Food Chemistry 18(1):128-129.

05002415 Gardiner, J.A.; Rhodes, R.C.; Adams, J.B., Jr.; Soboczenski, E.J. (1969) Synthesis and studies with 2-C14-labeled bromacil and terbacil. Journal of Agricultural and Food Chemistry 17(5):980-986.

05002583 Stryk, F.G. von; Zajacz, G.F. (1969) Determination and separation of some uracil herbicides by thin-layer chromatography. Journal of Chromatography 41(1):125-126.

05002771 Gardiner, J.A.; Reiser, R.W.; Sherman, H. (1969) Identification of the metabolites of bromacil in rat urine. Journal of Agricultural and Food Chemistry 17(5):967-973.

05012167 Helling, C.S.; Kaufman, D.D.; Dieter, C.T. (1971) Algae bioassay detection of pesticide mobility in soils. Weed Science 19(6): 685-690.

05013204 Wolf, D.C. (1974) Degradation of bromacil, terbacil, 2,4-D and atrazine in soil and pure culture and their effect on microbial activity. Dissertation Abstracts International B 34(10):4783-4784.

05013518 McGahen, J.W.; Hoffmann, C.E. (1963) Action of 5-bromo-3-sec-butyl-6-methyluracil as regards replacement of thymine in mouse DNA. Nature 199(4895):810-811.

05013519 McGahen, J.W.; Hoffmann, C.E. (1963) Action of 5-bromo-3-sec-butyl-6-methyluracil on Escherichia coli 15T. Nature 200(4906):571-572.

05013650 Moilanen, K.W.; Crosby, D.G. (1974) The photodecomposition of bromacil. Archives of Environmental Contamination and Toxicology 2(1):3-8.

05013999 Pease, H.L. (1966) Determination of bromacil residues. Journal of Agricultural and Food Chemistry 14(1):94-96.

05014217 Jolliffe, V.A.; Day, B.E.; Jordan, L.S.; Mann, J.D. (1967) Method of determining bromacil in soils and plant tissues. Journal of Agricultural and Food Chemistry 15(1):174-177.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Bromacil Standard

05014430 Midwest Research Institute (1975) Substitute Chemical Program: Initial Scientific and Minieconomic Review of Bromacil. Washington, D.C.: U.S. Environmental Protection Agency, Office of Pesticide Programs. (EPA-540/1-75-006; available from: NTIS, Springfield, VA; PB-241 801)

05014750 Shriver, J.W.; Bingham, S.W. (1973) Physiological effects of bromacil on Kentucky bluegrass and orchardgrass. Weed Science 21(3):212-217.

05014905 Siebert, D.; Lemperle, E. (1974) Genetic effects of herbicides: induction of mitotic gene conversion in Saccharomyces: cerevisiae:. Mutation Research 22:111-120.

05016141 Ebing, W. (1972) Routinemethode zur Duennschichtchromatographischen Identifizierung der Pestizidrueckstaende aus den Klassen der Triazine, Carbamate, Harnstoffe und Uracile. Routine method for identification of pesticide residues of triazine, carbamate, urea, and uracil type compounds by thin-layer chromatography Journal of Chromatography 65(3):533-545.

05016176 Wolf, D.C.; Martin, J.P. (1974) Microbial degradation of 2-carbon-14 bromacil and terbacil. Proceedings of the Soil Science Society of America 38(6):921-925.

05016657 Andersen, K.J.; Leighty, E.G.; Takahashi, M.T. (1972) Evaluation of herbicides for possible mutagenic properties. Journal of Agricultural and Food Chemistry 20(3):649-656.

05017170 Helling, C.S. (1971) Pesticide mobility in soils in Parameters of thin-layer chromatography. Proceedings of the Soil Science Society of America 35(5):732-737.

05019944 Ting, K.C.; Root, G.A.; Tichelaar, G.R. (1980) Gas-liquid chromatographic determination of bromacil residues. Journal of the Association of Official Analytical Chemists 63(1):43-46.

05020742 Grover, R.; Smith, A.E.; Korven, H.C. (1980) A comparison of chemical and cultural control of weeds in irrigation ditchbanks. Canadian Journal of Plant Science 60(1):185-195.